

Summary of the Proficiency Testing Committee Meeting January 14, 1998

The Proficiency Testing Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met on Wednesday, January 14, 1998, at 9 a.m. Eastern Standard Time (EST) as part of the Third NELAC Interim Meeting in Arlington, VA. The meeting was led by Dr. George Breuer of the Iowa State Hygienic Laboratory, designated representative for the chair, Ms. Anne Rhyne. A list of action items is given in Attachment A. A list of participants is given in Attachment B.

INTRODUCTION

Dr. Breuer began the meeting with introductions of the committee members. He stated that the purpose of the meeting was to discuss various issues and to provide the opportunity for the committee to receive comments. He announced that the committee had met the previous day with the members of EPA and NIST in order to iron out controversies and to identify other issues to be addressed. Dr. Breuer reviewed a revised agenda and stated that four new appendices would be discussed in the course of this meeting (Appendices E, F, G, and H).

CHAPTER 2 DISCUSSIONS

Proposed changes in Chapter 2, Sections 2.0 thru 2.2, were summarized. One comment was voiced related to the privatization effort. There was a request at the 1997 annual meeting that the PT Committee coordinate with the externalization process. This is being done and there is no further action on this issue at this time.

A question was raised about the accreditation/certification of laboratories (Chapter 2 and/or Chapter 4). The participant requested clarification on whether or not NELAC allows states to accredit or fail laboratories differently. Can a laboratory fail the standards and still be accredited? The PT Committee has set pass/fail criteria, but the accrediting authorities actually issue or revoke accreditation.

A participant addressed the frequency issue, asking NELAC to require only one, instead of two sets of standards be analyzed (like the Office of Water's program). The committee responded that this is being considered in order to decrease the burden on the states. There was a request for a national fixed schedule. There was discussion about the pros and cons of a fixed schedule, including cost and provisions for re-certification of laboratories that have failed or laboratories that have missed a scheduled test for some reason.

A participant remarked that distinction is needed between calendar days and working days. The committee agreed.

It was questioned whether or not there were any other programs that require PT certification. The participant suggested that the regulations be cited within the text of Chapter 2. Response

from the committee was that regulations are not cited within the section because they are subject to change.

With respect to analyte classification, the committee conceded that it does need to address the issue. The committee stated that it is waiting for standards from Office of Water's Water Supply and Water Pollution (WS and WP) programs. These standards will then be considered for adoption into the NELAC program. A logical start was to mimic the WS and WP programs and then add on to cover other areas.

One participant stated that he has problem with appendices for every different program. A committee member rebutted with the history of needing to address water programs first, since those are already existing. No appendices address solid waste or asbestos yet.

There was discussion of analyte-by-analyte versus analyte classes. Analyte-by-analyte is preferred because a standard that deals with all types of laboratories is desired. The standard must speak to smaller laboratories in addition to the large, full-service laboratories that cover all the analytes. If analyte classes can be addressed in appendices, then this will be done.

A participant questioned use of NELAC over NELAP (Section 2.2.1) NELAP is the program responsible for administrating the NELAC Standards. Committee agreed with this correction.

The proposed changes in Sections 2.3 and 2.4 were reviewed. There was some discussion about the reuse of PT samples. Once the program is in effect, samples cannot be reused for PT but may be used as known check samples.

A participant suggested that the committee strike the rest of the sentence after "...shall be determined by NELAC" (Section 2.3.2.1). This request was accepted by the committee.

Several suggestions were made by Mr. David Friedman, EPA. The suggestions were discussed and some of them were accepted as considerations for change. A written copy of these suggestions will be submitted to the committee, according to Mr. Friedman.

One suggestion was to put the discussion of statistical analysis (2.3.3.1) in appropriate sections of the standards so that it is not applicable to all. Another suggestion was that if the PTOB decides it needs it, then put it into their own standards. This chapter was written for any PTOB, not just for NIST. Discussion of 20 data points followed. A participant stated that if there is a problem with the sample, then someone must invalidate that sample. The committee responded that at least 20 data points are required to be able to make this decision—it is a minimum data set.

The changes in Sections 2.5 through 2.7 were reviewed. There were two major changes: change from 30 to 45 days (Section 2.5) and the elimination of Section 2.6.

There was a question regarding enforcability of restrictions against repetitive analysis of a PT sample. NELAC would like to ensure that laboratories treat PT samples in the same manner as environmental samples. Repetitive analysis by a laboratory may only indicate that they are trying to ensure that they pass. A participant pointed out that there are a wide variety of things that

laboratories do to ensure that they pass, such as compare analysis results with other laboratories, bring in better talent to analyze the samples, and perform repetitious analyses.

A participant pointed out that Section 2.7.5 was vague with respect to action that the accrediting authorities would take when a laboratory fails for the second time. The section allows accrediting authority too much leeway. The committee agreed that the language can use some revision and should be referred also to Chapter 4.

APPENDIX REVISIONS

The changes to Appendix A, “PT Provider Approval Criteria,” were reviewed. The committee first pointed out that Appendices A, B, C and D are very closely tied to the operation of the PTOB. Not all the issues have been resolved. The committee is waiting for additional information before this can be resolved. Change of verbiage from “sample design” to “sample formulation” due to ambiguous definition of the word design was done. Additional suggestions for clarification are welcome.

There was a request for acronyms to be defined somewhere within the document. A committee member said that they would try to clarify some of the jargon used in the document.

The changes to Appendix B, “PT Sample Design & Acceptance Guidelines,” were reviewed. Two comments were rejected by the committee, three were deferred, and one was incorporated. The comment that was incorporated was related to verifying sample stability before use in the study (B.3.0).

A participant pointed out that the existing language in Appendix B is very general and questioned the level of detail required. Committee responded that in certain cases, specific language is appropriate, suggestions are welcome. The committee is trying to provide protocols.

The changes to Appendix C, “PT Acceptance Criteria,” were reviewed. One major revision was that C.5.5 was emitted entirely because it was unnecessary.

The following question was raised. Will you automatically fail if your instrument crashes while you are participating in a study? The committee said that text was initially added to prevent a laboratory from changing their mind about participation at the last minute. The accrediting authority can make adjustments in specific cases.

Changes to Appendix D, “Proficiency Testing Oversight Body” were discussed by the committee. Two changes were incorporated and two were deferred. The database will continue to be maintained by the EPA, but details are not yet worked out. Once final, they will be incorporated into the standard. Appendix will be revised to cover situations where NIST will not be the PTOB. NIST Handbook 150-XX will be reviewed to ensure there is no conflict with Appendix D. This handbook is available, and will be discussed at the open meeting on Friday. One participant pointed out that we need to be very careful that this meets the needs of NELAC, and not just the needs of EPA and NIST. The committee agreed.

NEW APPENDICES

Copies of new Appendices E, F and G to Chapter 2 were handed out. Since this is the first release of these appendices, the committee encouraged comments. Inputs were requested early so that the committee will have ample time to discuss them before proposing these appendices at the annual meeting.

Appendix E, "Microbiology," was reviewed. This appendix outlines the requirements for microbiological proficiency testing under the Safe Drinking Water and Clean Water Acts. One participant was concerned that if a laboratory misses one part of the test, the laboratory has failed the entire test. Following some discussion, the committee requested a pattern that was more appropriate to be submitted, and the participant agreed. Higher numbers of PT samples allow for greater latitude in the number of misses a laboratory is allowed. It comes down to a choice of how many samples to require. For example, 6 samples and no misses, or 10 samples allowing 1 or 2 misses. Discussion followed on the number of blanks a provider would be allowed to send.

Appendix F, "Radiochemistry,," was reviewed. This appendix is basically a compilation of comments received. The appendix outlines variances from Chapter 2 deemed necessary for radiochemical proficiency testing under NELAP. USEPA program requirements, for example for Safe Drinking Water Act compliance, will take precedence over the requirements set forth in this appendix.

Appendix G, "Biology (Environmental Toxicology)," was reviewed. This appendix defines the criteria applying the PT program to the whole effluent toxicity, sediment toxicity, and soils toxicity programs. Consolidation is needed with the EPA program. Some of the Section 2 changes relate to this appendix also, specifically Sections 2.4.1, 2.5, 2.7.2, and 2.7.3.

The committee addressed Appendix H, "Air", which is not yet available. Fundamental differences exist between the EPA Office of Air's program and NELAP that the committee needs to address. The subcommittee welcomes others to help develop this appendix. Participants were invited to indicate their interest on the sign-up sheet.

OTHER DISCUSSIONS

The committee briefly discussed NELAC's Analyte Acceptance Limits, which are covered in Appendix C.

There are a number of potential providers, but they are waiting to find out more specifics of what will be required before they can make the business decision of whether or not it is profitable enough for them to want to be a PT provider. Market pressure is a factor. The marketplace will also play a role in assuring quality providers.

As it is, laboratories can choose their PT provider, and the Proficiency Testing Oversight Body (PTOB) will oversee them. Values will vary between providers, but the analytical techniques will be the same. Reciprocity is also an issue for the states. If a state selects one PT provider for all

its laboratories, there is a lot of liability involved. This problem would be resolved by allowing the laboratories to choose their own PT provider.

It was asked whether or not it is possible for laboratory failure rates to be incorporated into the national database. The committee response was that failure rate is not a true indicator of how good a PT provider is. Some PT providers may actually be attracting “better” laboratories. The participant then suggested the addition of a field to indicate who the provider is for each laboratory. Committee responded that this information should not be public, because laboratories may be searching for “easy” providers. The question was raised “how do you monitor performance of the providers?” The PT Committee has discussed this, but has not decided on a resolution.

Nonperformance is a failure -- it may be desirable to revise or create some other guidance to address natural disaster. This should be referred to Chapter 4.

ACTION ITEMS
Proficiency Testing Committee
January 14, 1998

Item No.	Action Item	Date to be Completed
1.	Clarify use of jargon within document and define acronyms.	5/1/98
2.	Revise text to specify calendar days or working days.	5/1/98
3.	Form a subcommittee for Appendix H, "Air." (Attendees should have indicated interest on attendance sheet.)	5/1/98
4.	Address frequency issues (number of studies per year, fixed schedule, supplemental studies).	5/1/98
5.	Resolve question of accrediting authority's ability to select a single PT provider for all laboratories within the state.	5/1/98
6.	Refer significant comments on accrediting authority actions to Accreditation Process Committee (Chapter 4).	5/1/98
7.	Revise appendices as appropriate pending issuance of USEPA National Standards and NIST Handbook 150 as part of cooperative effort.	5/1/98
8.	Do we need a minimum of 20 data points?	5/1/98
9.	David Friedman will provide comments.	

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January 14, 1998

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